

Remarks

Claims 38-70 were pending in this application as of the July 19, 2007 mailing date of the present Office Action. Claims 38, 39, 42, 44-46, 48-51, 55 and 63 are here amended, claims 71-72 are added, leaving claims 38-72 in the application.

Claim Objections

Claims 44, 45, 51, 53, 59 and 63 were objected to because of informalities. These informalities are resolved in the amendments to these claims set forth above.

Claim Rejections – 35 U.S.C. § 112 (first paragraph)

Claims 39 and 50 were rejected as lacking support in the specification for use of the system and apparatus of the invention to implement “relaxation therapy” and “cognitive behavioral therapy”. These claims have been amended to delete the reference cognitive behavioral therapy. Also, they have been amended to refer to “relaxation training” rather than “relaxation therapy”. Support for the latter change appears, e.g., in the specification at page 2, line 13.

Claim 44 was rejected and lacking support for a “maintenance mode”. This claim has been amended to refer to a “sleep maintenance mode”. Thus, in paragraph (c) of claim 44 it is explained that the subject is designated to be in a sleep maintenance mode if any sleep of at least a second predetermined number of contiguous epochs is achieved. This is consistent with the explanation on, e.g., page 14 of the specification that stimulus control is an effective intervention for sleep maintenance insomnia and that the automated implementation of stimulus control of the invention is directed to treating, *inter alia* sleep maintenance insomnia. Sleep maintenance insomnia would, of course, be a condition in which the subject is not in a sleep maintenance mode.

The rejections of claims 40 and 45 are presumed to be based upon the dependence of these claims, respectively, on claims 39 and 44. If these claims were rejected for another reasons, clarification is respectfully requested.

Claim Rejections – 35 U.S.C. § 112 (second paragraph)

Claim 38 was rejected in regard to the limitation “the steps of the behavior therapy” in line 7. This rejection is met by removing the language “steps of the”.

Claim 46 was rejected for the reference to “the behavioral therapy parameters” in line 1-2. This rejection is met by removing the language “parameters are” from the claim.

Claim 48 was rejected as lacking antecedent basis for the limitation “the rules of the stimulus therapy” in lines 4-6. This rejection is met by removing the language “the rules of”.

Claim 49 was rejected as lacking antecedent bases for the limitations “the program parameters” in line 3 and “the rules of the sleep restriction therapy” in line 5. These rejections are met by adding the following language to the preamble: “in which program parameters are defined and sleep restriction therapy rules are applied to implement the therapy.” Support for this amendment appears, e.g., at pages 25-28 of the specification which explains the application of sleep restriction therapy, references program parameters, and delineates rules applied to implement the behavioral therapy.

Claims 56 and 57 were rejected as lacking antecedent basis for the limitation “means are provided for turning off any alert” in line 2 of these claims. This rejection is met by the amendment of Claim 55 to replace the term “indication of” with “alert as to”.

Claim Rejections – 35 U.S.C. § 102

Claims 38-43, 46-54 and 58-69 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,928,138 (Halyak).

Claim 38

The Examiner argues that Halyak at col. 2, l. 49-58 anticipates the following feature of claim 38:

“an automated system for facilitating the implementation of behavioral therapy that uses information indicative of a subject's wake/sleep state to improve the subject's sleep or sleep hygiene, including subjects with insomnia or other sleep complaints, comprising: passive wake/sleep determination means for producing information indicative of the subject's wake/sleep state.”

He also argues that Halyak at col. 4, l. 1-24 anticipates the following feature of claim 38:

“means for implementing the steps of the behavioral therapy utilizing the wake/sleep information.”

Applicants respectfully disagree.

First, Halyak monitors only changes in body resistance and gently wakes the subject when large changes are detected during a pre-set time interval. Halyak does not teach or suggest passively determining wake and sleep states since this reference is just looking for large changes in body resistance that tend to correlate with times that the subject can be awakened gently.

Furthermore, Halyak (col. 4, l. 11-24) has no teaching whatsoever regarding "means for implementing the steps of the behavioral therapy utilizing the wake/sleep information." Halyak describes the workings of a control unit that contains an alarm or awakening means, and may also include a display and a printer. These devices are not used to implement any behavioral therapy. Nowhere does Halyak describe the implementation of a behavioral therapy.

The Halyak invention is nothing more than an alarm clock that does not constitute a "behavioral therapy." Behavioral therapy comprises:

- A therapeutic method that focuses on modifying or "unlearning" a maladaptive behavior without consideration of any underlying causes.
- Deals directly with immediate and specific problems. Problem behaviors are identified and discouraged; rewarding behaviors are encouraged.
- A treatment plan that is designed for a particular person and targets a specific problem or behavior for modification regardless of diagnosis.

In summary, it is submitted that Halyak's description of an alarm clock that is based on the monitoring of changes in body resistance does not anticipate or render obvious the automated implementation of a behavioral therapy using a passive means for sleep/wake detection as set forth in claim 38.

Claims 39-41, 43, 46

These dependent claims are believed to be patentable based on patentability of claim 38 from which they depend, for the reasons explained above. Additionally, it is noted that the Examiner argues that Halyak teaches of a combination of therapies in col. 2, l. 59 to col. 3, l. 3 wherein information of the stimulus (diet, exercise, etc) and restriction/relaxation (alarm) are used. He also argues that Halyak's system uses EEG's, heart rate, movement

sensors, galvanic skin response, and other parameters for sleep research (col. 3, l. 58-67), where the user can calibrate the values that are most efficacious for the user (col. 5, l. 10-15).

This ignores the specific meaning of the term “stimulus control” in psychology, namely:

“Stimulus control therapy is a specific type of cognitive behavioral therapy that is based on the assumption that insomnia is due to increased tension and arousal that occurs as a conditioned response to the stimulus of the sleep environment. Spending time in bed, wide awake, strengthens the association between wakefulness and the bedroom, leading to continued insomnia. Therefore, the primary goal is to have the patient in bed only when drowsy or asleep. SCT is aimed at breaking the association between wakefulness and the sleep environment.”

While Halyak generally provides the user with data concerning their awakening points and interruptions from factors such as diet, exercise and stress, this should not be confused with the term “stimulus” as employed in the context of the present invention. Halyak is describing lifestyle factors (diet and exercise) and not teaching or suggesting specific cues as in the present invention (such as the bed or bedroom being associated with not sleeping) that evoke or occasion a particular response.

Furthermore, merely using an alarm to wake the subject does not constitute sleep restriction, which also has specific meaning in psychology. An alarm, in and of itself, is not necessarily a sleep restriction (or a “restriction/relaxation” as used by the examiner). It all depends on how the alarm is used. The alarm used in Halyak is intended to wake the subject much like a conventional alarm clock would, but in the appropriate time window (at the first perceived optimal opportunity for a gentle awakening). This in no way constitutes a sleep restriction as that term is understood in psychology or as it is used in the present application.

For example, when the present invention is running in Stimulus Control mode, it uses the alarm in these claims to alert an already awake subject to get out of bed in accordance with Stimulus Control instructions. Thus it does not constitute an alarm clock because, by the functioning of the device, the subject is NOT asleep during the alert. When the present invention is running in Sleep Restriction mode, it uses the alarm to alert the subject to get out of bed after a maximum time in bed has been achieved, regardless of whether they are asleep

or awake. The amount of time allowed in bed when running Sleep Restriction is determined by wake/sleep information from a previous period of time as explained in the application.

With specific reference to claim 41, Halyak does not teach or suggest determining of an optimal therapy from a choice of therapies, he is just concerned with a wakeup time. This, of course, is not surprising since Halyak is not describing any therapies, he is just describing an alarm clock.

It is further noted that while Halyak describes a number of methods for accomplishing his invention, Halyak is not explicitly monitoring wake/sleep using any of these methods. According to Halyak, "The invention is able to track optimal waking points, which tend to coincide with sleep cycles." (Underlining added). (Col. 2, l. 59-60). Halyak is not describing wake/sleep detection and is using this data for an entirely different purpose, namely to implement an alarm clock, as discussed above.

In reference to claim 46, it is noted that Halyak appears to describe the user making changes to the threshold used to wake them. For example, the user can make the system more or less sensitive to changes in resistance. Claim 46 focuses on changes to the parameters of a behavioral therapy and this is completely different from Halyak. Each behavioral therapy has certain parameters and the user is allowed to make changes to these parameters to best fit with their needs and comfort. For example, the automatically determined Sleep Restriction parameters (based on wake/sleep information as described in the present application) may choose a limit of four hours in bed per night for the user. Thus allows the user (or a clinician) to make this parameter higher or lower to accommodate the needs of a given individual using the system.

Claim 42

The Examiner argues that claim 42 fails to further limit the claimed system. Claim 42 has been amended to make clear that the drug therapy is part of the claimed system and not an intended use as suggested by the Examiner.

Claim 47

The Examiner argues that Halyak at col. 3, l. 58 to col. 4, l.55 discloses an apparatus for facilitating the implementation of behavioral therapy for a subject seeking to improve the subject's sleep or sleep hygiene, including subjects with insomnia or other sleep complaints, comprising means for processing information taken from the group consisting of: EEG, EKG,

EMG, EOG, actigraphy, body movement, galvanic skin response, respiratory changes, eye movements and combinations of two or more thereof to determine the subject's wake/sleep state; and means for implementing the behavioral therapy utilizing the wake/sleep state information.

As noted above, Halyak only monitors changes in body resistance and gently wakes the subject when large changes are detected during a pre-set time interval. Halyak does not teach or suggest passively determining wake and sleep states. Furthermore, Halyak does not implement steps of a behavioral therapy utilizing wake/sleep information. Halyak describes the workings of a control unit that contains an alarm or awakening means, and may also include a display and a printer. These devices are not used to implement any behavioral therapy. The Halyak invention is an alarm clock that does not constitute a behavioral therapy.

Claims 48-54, 58-69

These dependent claims are believed to be patentable based on patentability of independent claim 47 from which they depend.

Claim Rejections – 35 U.S.C. § 103

Claims 55-57 and 70 stand rejected as obvious over Halyak in view of U.S. Patent No. 6,392,962 to Wyatt.

The Examiner argues that Halyak meets the limitations of these dependent claims but fails to mention whether the subject is in bed or not. Wyatt, however, describes a sleep disorder treatment involving a timer that can be attached to an insomniac's bed, etc (col. 6, l. 5-10), and a touch pad (24) that engages the time to be measured when connected and stops when the pads are disconnected (col. 6, l. 43-52). The timer located on the bed can either record time when the pads are connected or disconnected (col. 6, l. 53 to col. 7, l. 9) and thus can acquire wake/wake information and can determine if the subject is in bed and display it on either a monitor or printer.

The Examiner argues from this that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Wyatt with that of Halyak to develop a sleep therapy system and apparatus that is able to determine

whether or not the user is in bed along with their wake/sleep state information. Applicants respectfully disagree.

First, these dependent claims are believed to be patentable based on patentability of independent claim 47 from which they depend. Additionally, Wyatt describes a dead-man's switch combined with a timer to detect wake/sleep (at least the first transition from wake to sleep). This apparatus will not monitor wake/sleep throughout the night. Furthermore, the invention described in Wyatt, even if it were to be considered a wake/sleep detector, is not *passive*. Wyatt's process is active whereby the user needs to perform an action (i.e. holding the contacts closed) in order to detect wake/sleep.

Claim 55 in particular is directed to collecting in-bed information along with wake/sleep information and neither Halyak nor Wyatt has an in-bed sensor. In Wyatt (col. 6 l. 5-10), a method of attaching the timing device to a location other than attached to the user (i.e. connected to the bed, etc.) is described. This is not an in-bed sensor and, in fact, Wyatt does not claim that it is an in-bed sensor. It is still a dead-man's switch, connected to the user where the timing device that is responsive to the status (open or closed) of the dead-man's switch is remotely located.

Furthermore, Wyatt at col. 6, l. 43-52 and col. 6, l. 53 to col. 7, l. 9 still does not describe an in-bed sensor. In Col. 6, he describes replacing the dead-man's switch attached to the user's hand with a touch pad that the user is expected to keep in contact with a body part. The presumption is that the subject will move when they fall asleep, the time will then start or stop, which is a very primitive means of active wake/sleep detection. Again, however, this is not an in-bed sensor and further, this is not a passive device. The timer of Wyatt is not responsive to whether the subject is "in-bed," it is responsive to the user moving after falling asleep in such a way as to break contact with a sensing device. Breaking contact with the sensor could be due to the subject: (a) falling asleep; or (b) leaving bed because they are awake. The device cannot distinguish between these two actions and as such, this device cannot be used as an in-bed sensor.

In view of the amendments to the claims and the arguments set forth above, the application is believed to be in good and proper form for allowance, and therefore the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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Date: October 19, 2007

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